Complete Summary

GUIDELINE TITLE

Trauma and post-traumatic stress disorder in patients with HIV/AIDS. Mental health care for people with HIV infection.

BIBLIOGRAPHIC SOURCE(S)

Trauma and post-traumatic stress disorder in patients with HIV/AIDS (updated online 2004 Sep). In: Mental health care for people with HIV infection: HIV clinical guidelines for the primary care practitioner. New York (NY): New York State Department of Health; 2001 Mar. p. 69-75.

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- On May 12, 2006, GlaxoSmithKline (GSK) and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of changes to the Clinical Worsening and Suicide Risk subsection of the WARNINGS section in the prescribing Information for Paxil and Paxil CR. These labeling changes relate to adult patients, particularly those who are younger adults.

  A recent meta-analysis conducted of suicidal behavior and ideation in placebo-controlled clinical trials of paroxetine in adult patients with psychiatric disorders including Major Depressive Disorder (MDD), other depression and non-depression disorders. Results of this analysis showed a higher frequency of suicidal behavior in young adults treated with paroxetine compared with placebo. Further, in the analysis of adults with MDD (all ages), the frequency of suicidal behavior was higher in patients treated with paroxetine compared with placebo. This difference was statistically significant; however, as the absolute number and incidence of events are small, these data should be interpreted with caution. All of the reported events of suicidal behavior in the adult patients with MDD were non-fatal suicide attempts, and the majority of these attempts (8 of 11) were in younger adults aged 18-30. These MDD data suggest that the higher frequency observed in the younger adult population across psychiatric disorders may extend beyond the age of 24.

It is important that all patients, especially young adults and those who are improving, receive careful monitoring during paroxetine therapy regardless of the condition being treated. See the FDA Web site for more information.

- On December 8, 2005, the U.S. Food and Drug Administration (FDA) has determined that exposure to paroxetine in the first trimester of pregnancy may increase the risk for congenital malformations, particularly cardiac malformations. At the FDA's request, the manufacturer has changed paroxetine's pregnancy category from C to D and added new data and recommendations to the WARNINGS section of paroxetine's prescribing information. FDA is awaiting the final results of the recent studies and accruing additional data related to the use of paroxetine in pregnancy in order to better characterize the risk for congenital malformations associated with paroxetine.

  Physicians who are caring for women receiving paroxetine should alert them to the potential risk to the fetus if they plan to become pregnant or are currently in their first trimester of pregnancy. Discontinuing paroxetine therapy should be considered for these patients. Women who are pregnant, or planning a pregnancy, and currently taking paroxetine should consult with their physician about whether to continue taking it. Women should not stop the drug without discussing the best way to do that with their physician. See the FDA Web site for more information.

- On September 27, 2005, GlaxoSmithKline (GSK) and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of changes to the Pregnancy/PRECAUTIONS section of the Prescribing Information for Paxil and Paxil CR Controlled-Release Tablets to describe the results of a GSK retrospective epidemiologic study of major congenital malformations in infants born to women taking antidepressants during the first trimester of pregnancy. This study suggested an increase in the risk of overall major congenital malformations for paroxetine as compared to other antidepressants [OR 2.2; 95% confidence interval, 1.34-3.63]. Healthcare professionals are advised to carefully weigh the potential risks and benefits of using paroxetine therapy in women during pregnancy and to discuss these findings as well as treatment alternatives with their patients. See the FDA Web site for more information.
- On July 1, 2005, in response to recent scientific publications that report the possibility of increased risk of suicidal behavior in adults treated with antidepressants, the U.S. Food and Drug Administration (FDA) issued a Public Health Advisory to update patients and healthcare providers with the latest information on this subject. Even before the publication of these recent reports, FDA had already begun the process of reviewing available data to determine whether there is an increased risk of suicidal behavior in adults taking antidepressants. The Agency has asked manufacturers to provide information from their trials using an approach similar to that used in the evaluation of the risk of suicidal behavior in the pediatric population taking antidepressants. This effort will involve hundreds of clinical trials and may take more than a year to complete. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Human immunodeficiency virus infection/acquired immune deficiency syndrome (HIV/AIDS)
- Acute stress disorder (ASD)
- Post-traumatic stress disorder (PTSD)

GUIDELINE CATEGORY

Diagnosis
Management
Screening

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Infectious Diseases
Internal Medicine
Psychiatry
Psychology

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To provide guidelines for the diagnosis and management of post-traumatic stress disorder (PTSD) and acute stress disorder (ASD) in patients with human

immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) in primary care settings

TARGET POPULATION

Patients with human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS)

INTERVENTIONS AND PRACTICES CONSIDERED

1. Screening for post-traumatic stress disorder (PTSD) annually or as clinically indicated
2. Use of Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria
3. Screening for other mental disorders
4. Referral to a mental health professional
5. Medications (sertraline, paroxetine)

   Note: Long-term benzodiazepines are not a preferred treatment

6. Psychotherapy including exposure therapy, anxiety management programs, and cognitive therapy

MAJOR OUTCOMES CONSIDERED

- Prevalence of post-traumatic stress disorder (PTSD) in human immunodeficiency virus (HIV)-infected patients
- Effectiveness of treatment on relieving symptoms of PTSD

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Human Immunodeficiency Virus (HIV) Guidelines Program works directly with committees composed of HIV Specialists to develop clinical practice guidelines. These specialists represent different disciplines associated with HIV care, including infectious diseases, family medicine, obstetrics and gynecology, among others. Generally, committees meet in person 3 to 4 times per year, and otherwise conduct business through monthly conference calls.

Committees meet to determine priorities of content, review literature, and weigh evidence for a given topic. These discussions are followed by careful deliberation to craft recommendations that can guide HIV primary care practitioners in the delivery of HIV care. Decision making occurs by consensus. When sufficient evidence is unavailable to support a specific recommendation that addresses an important component of HIV care, the group relies on their collective best practice experience to develop the final statement. The text is then drafted by one member, reviewed and modified by the committee, edited by medical writers, and then submitted for peer review.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Key Point

Exposure to traumatic events can lead to increased risk-taking behavior, including substance use, unsafe sexual practices, and difficulty forming therapeutic relationships with medical personnel.

Post-Traumatic Stress Disorder (PTSD)

Key Point

The likelihood of a patient developing PTSD varies according to the vulnerability of the affected person and the severity of the stressor.

Diagnosis

The primary care clinician should screen for PTSD annually or more often as clinically indicated.

Clinicians should use the criteria listed in the Diagnostic and Statistical Manual of Mental Disorders-IV (DSM-IV) for a diagnosis of PTSD in patients with human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) (see table below).

Clinicians should screen patients with PTSD or significant trauma histories for clinical depression, anxiety disorders, or alcohol or other substance use disorders.

Diagnostic Criteria for Post-Traumatic Stress Disorder
A. The person has been exposed to a traumatic event in which both of the following were present: 1. The person experienced, witnessed, or was confronted with an event or events that involved actual or threatened death, serious injury, or a threat to the physical integrity of self or others. 2. The person's response involved intense fear, helplessness, or horror. B. The traumatic event is persistently re-experienced in one (or more) of the following ways: 1. Recurrent and intrusive distressing recollections of the event including images, thoughts, or perceptions 2. Recurrent distressing dreams of the event 3. Acting or feeling as if the traumatic event were recurring (e.g., a sense of reliving the experience, illusions, hallucinations, and dissociative flashback episodes, including those that occur upon awakening or when intoxicated) 4. Intense psychological distress at exposure to internal or external cues that symbolize or resemble an aspect of the traumatic event

Diagnostic Criteria for Post-Traumatic Stress Disorder
5. Physiological reactivity upon exposure to internal or external cues that symbolize or resemble an aspect of the traumatic event C. Persistent avoidance of stimuli associated with the trauma and numbing of general responsiveness (not present before the trauma) as indicated by three (or more) of the following: 1. Efforts to avoid thoughts, feelings, or conversations associated with the trauma 2. Efforts to avoid activities, places, or people that arouse recollections of the trauma 3. Inability to recall an important aspect of the trauma 4. Markedly diminished interest or participation in significant activities 5. Feeling of detachment or estrangement from others 6. Restricted range of affect (e.g., unable to have loving feelings) 7. Sense of a foreshortened future (e.g., does not expect to have a career, marriage, children, or a normal life span) D. Persistent symptoms of increased arousal (not present before the trauma) as indicated by two (or more) of the following: 1. Difficulty falling or staying asleep 2. Irritability or outbursts of anger 3. Difficulty concentrating 4. Hypervigilance 5. Exaggerated startle response E. Duration of the disturbance (symptoms in criteria B, C, and D) is more than 1 month. F. The disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Key Point

Patients with PTSD may have dissociative symptoms, which may be mistaken for HIV-related dementia or other HIV-related neuropsychiatric disorders.

Management of Survivors of Trauma

Clinicians should refer patients with symptoms of PTSD to a mental health professional as soon as possible for evaluation for psychotherapy or other forms of psychiatric treatment. The goal of treatment should be to reduce symptoms and fully reintegrate a safe sense of self.

If specialized services are unavailable, the primary care clinician should prescribe medications (see Appendix I in the "Companion Documents" field) and monitor the degree of improvement achieved with this strategy alone.

During the acute phase of treatment, clinicians should assess the patient's risk for harm to him/herself or others.

Key Point

Although patients with PTSD may seek help for associated somatic symptoms, they may perceive medical intervention as intrusive and thus re-traumatizing.

Acute Stress Disorder (ASD)

For patients who meet the criteria for ASD, clinicians should follow the same guidelines as those recommended for management of PTSD (see "Management of Survivors of Trauma" section above).

Diagnostic Criteria for Acute Stress Disorder
A. The person has been exposed to a traumatic event in which both of the following were present: 1. The person experienced, witnessed, or was confronted with an event or events that involved actual or threatened death, serious injury, or a threat to the physical integrity of self or others 2. The person's response involved intense fear, helplessness, or horror B. Either while experiencing or after experiencing the distressing event, the individual has three (or more) of the following dissociative symptoms: 1. A subjective sense of numbing, detachment, or absence of emotional responsiveness 2. A reduction in awareness of his/her surroundings (e.g., "being in a daze") 3. Derealization 4. Depersonalization 5. Dissociative amnesia (i.e., inability to recall an important aspect of the trauma) C. The traumatic event is persistently re-experienced in at least one of the following ways: Recurrent images, thoughts, dreams, illusions, flashback episodes, or a sense of reliving the experience; or distress on exposure to reminders of the traumatic event D. Marked avoidance of stimuli that arouse recollections of the trauma (e.g., thoughts, feelings, conversations, activities, places, people) E. Marked symptoms of anxiety or increased arousal (e.g., difficulty sleeping, irritability, poor concentration, hypervigilance, exaggerated startle response, motor restlessness) F. The disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning or impairs the individual's ability to pursue some necessary task, such as obtaining necessary assistance or mobilizing personal resources by telling family members about the traumatic experience G. The disturbance lasts for a minimum of 2 days and a maximum of 4 weeks and occurs within 4 weeks of the traumatic event H. The disturbance is not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition, is not better accounted for by brief psychotic disorder, and is not merely an exacerbation of a preexisting Axis I or Axis II

Diagnostic Criteria for Acute Stress Disorder
disorder

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate diagnosis and management of post-traumatic stress disorder and acute stress disorder in patients with human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) in primary care settings.
- Controlled and open studies of various selective serotonin reuptake inhibitors (SSRIs) as well as other classes of antidepressants have shown benefit in treating post-traumatic stress disorder (PTSD) symptoms. Open trial studies of mood stabilizers have also shown some benefits.

POTENTIAL HARMS

If benzodiazepines are prescribed, careful monitoring is required due to the potential for abuse and concerns about disinhibition in those with significant dissociative symptoms.

Refer to Appendix I in the "Companion Document" field for side effect profile and drug-drug interactions.

CONTRAINDICATIONS

CONTRAINDICATIONS

Paroxetine should be avoided in patients less than 18 years old because of its possible association with increased suicide risk.

Refer to Appendix I in the "Companion Document" field for contraindications between human immunodeficiency virus (HIV)-related medications and psychotropic medications.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Following the development and dissemination of guidelines, the next crucial steps are adoption and implementation. Once practitioners become familiar with the content of guidelines, they can then consider how to change the ways in which they take care of their patients. This may involve changing systems that are part of the office or clinic in which they practice. Changes may be implemented rapidly, especially when clear outcomes have been demonstrated to result from the new practice such as prescribing new medication regimens. In other cases, such as diagnostic screening, or oral health delivery, however, barriers emerge which prevent effective implementation. Strategies to promote implementation, such as through quality of care monitoring or dissemination of best practices, are listed and illustrated in the companion document to the original guideline (HIV clinical practice guidelines, New York State Department of Health; 2003), which portrays New York's HIV Guidelines Program. The general implementation strategy is outlined below.

- Statement of purpose and goal to encourage adoption and implementation of guidelines into clinical practice by target audience.
- Define target audience (providers, consumers, support service providers).
    - Are there groups within this audience that need to be identified and approached with different strategies (e.g., HIV Specialists, family practitioners, minority providers, professional groups, rural-based providers)?
- Define implementation methods.
    - What are the best methods to reach these specific groups (e.g., performance measurement consumer materials, media, conferences)?
- Determine appropriate implementation processes.
    - What steps need to be taken to make these activities happen?
    - What necessary processes are internal to the organization (e.g., coordination with colleagues, monitoring of activities)?
    - What necessary processes are external to the organization (e.g., meetings with external groups, conferences)?
    - Are there opinion leaders that can be identified from the target audience that can champion the topic and influence opinion?
- Monitor progress.
    - What is the flow of activities associated with the implementation process and which can be tracked to monitor the process?
- Evaluate.
    - Did the processes and strategies work? Were the guidelines implemented?
    - What could be improved in future endeavors?

IMPLEMENTATION TOOLS

Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Trauma and post-traumatic stress disorder in patients with HIV/AIDS (updated online 2004 Sep). In: Mental health care for people with HIV infection: HIV clinical guidelines for the primary care practitioner. New York (NY): New York State Department of Health; 2001 Mar. p. 69-75.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Sep

GUIDELINE DEVELOPER(S)

New York State Department of Health - State/Local Government Agency [U.S.]

SOURCE(S) OF FUNDING

New York State Department of Health

GUIDELINE COMMITTEE

Mental Health Guidelines Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- HIV clinical practice guidelines. New York (NY): New York State Department of Health; 2003. 36 p. Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.
- Appendix I: interactions between HIV-related medications and psychotropic medications: indications and contraindications. New York (NY): New York State Department of Health; 2001 Mar. Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.
- Appendix II: HIV-related causes of psychiatric symptoms: differential diagnosis. New York (NY): New York State Department of Health; 2001 Mar. Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.
- Appendix III: rating scales. New York (NY): New York State Department of Health; 2001 Mar. Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.
- Appendix IV: mental health care resources in New York State. New York (NY): New York State Department of Health; 2001 Mar. Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.
- Appendix V: syringe access resources in New York State. New York (NY): New York State Department of Health; 2001 Mar. Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.
- Appendix VI: permanency planning and transitional services. New York (NY): New York State Department of Health; 2001 Mar. Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on May 5, 2005. This summary was updated by ECRI on August 15, 2005, following the U.S. Food and Drug Administration advisory on antidepressant medications. This summary was updated by ECRI on August 15, 2005, following the U.S. Food and Drug Administration advisory on antidepressant medications. This summary was updated by ECRI on October 3, 2005, following the U.S. Food and Drug Administration advisory on Paxil (paroxetine) This summary was updated by ECRI on December 12, 2005, following the U.S. Food and Drug Administration advisory on Paroxetine HCL - Paxil and generic paroxetine. This summary was updated by

ECRI on May 31, 2006 following the U.S. Food and Drug Administration advisory on Paxil (paroxetine hydrochloride).

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